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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC., **Plaintiff,** **v.** **ROXANE LABORATORIES, INC.,** **Defendant.**	**Civil Action No. 10-6108 (ES)(JAD)** **(Filed Electronically)** **Oral Argument Requested**

JAZZ'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO BIFURCATE CLAIMS RELATING TO THE '730 PATENT FAMILY

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I. INTRODUCTION

Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz") submits this memorandum in support of its motion to bifurcate and stay claims related to the '730 patent family.[1] Those patents claim methods of safely using and administering certain prescription drugs prone to abuse, misuse, and/or diversion. The claims of the '730 patent family cover Jazz's Risk Evaluation and Mitigation Strategy ("REMS") associated with the use of Jazz's XYREM® product. [redacted] Proceeding with those claims now will thus result in a substantial misuse of the Court's and the parties' resources [redacted]

II. STATEMENT OF FACTS

Jazz makes and sells XYREM®—the only FDA-approved treatment for cataplexy (sudden loss of muscle tone) and excessive daytime sleepiness in patients with the sleep disorder narcolepsy. The active ingredient in XYREM® is sodium oxybate, the sodium salt of gamma-hydroxybutyrate or "GHB." While useful for treating patients with narcolepsy, GHB has a notorious past based on its abuse as a recreational drug and its association with drug-facilitated

[1] The '730 patent family includes U.S. Patent Nos. 7,668,730, 7,765,106, 7,765,107 and 7,895,059. The remaining patents-in-suit are U.S. Patent Nos. 6,472,431, 6,780,889, 7,262,219, 7,851,506, 8,263,650, and 8,324,275 (collectively, "the '431 patent family").

sexual assaults.[2] As a result of its past abuse, the FDA required a restricted distribution system for XYREM® as a condition of marketing the drug.[3] The FDA will similarly not approve a generic version of XYREM® without an acceptable REMS system. See 21 U.S.C. § 355-1(i)(1)(B)(i)-(ii).

Thus, to obtain FDA approval to market its proposed ANDA product, Roxane must propose and receive FDA approval of a REMS for its product. *See* 21 U.S.C. § 355-1(i)(1). Roxane must either use the same REMS as XYREM®, or certify to the FDA that: (1) the burden of using the same REMS outweighs the benefits; or (2) parts of the XYREM® REMS are patented (or trade secrets) and Roxane has been unable to obtain a license. *See* 21 U.S.C. § 355-1(i)(1)(B)(i)-(ii). Even if the FDA waives the shared REMS requirement, a separate REMS must be "comparable" to the approved REMS. *Id.*

[redacted]

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[2] *See* Drug Enforcement Administration, WHO Questionnaire For Review of Dependence-Producing Psychoactive Substances by the 32nd Expert Committee on Drug Dependence, May 17, 2000, at Sec. 2.2.1-2.2.3, available at http://www.fda.gov/ohrms/dockets/dailys/00/may00/053000/c000003.pdf (last visited December 3, 2013).

[3] Today, such pharmaceutical restricted distribution systems are referred to as "REMS." XYREM® was included on the list of products deemed by the FDA to have in effect an approved REMS under 21 U.S.C. § 355-1. *See* 73 Fed. Reg. 16314 (Mar. 27, 2008).

[4] [redacted] "Ex. __" refers to the Declaration of Gabriel P. Brier, submitted herewith.

[redacted] Alternatively, trial on the other patents-in-suit may resolve all issues between the parties. As such, Jazz respectfully requests that the Court bifurcate and stay claims related to the '730 patent family [redacted]

III. ARGUMENT

A. Legal Standards

Fed. R. Civ. P. 42(b) states that, "[f]or convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims." Fed. R. Civ. P. 42(b). The decision to bifurcate is within the Court's "broad discretion," and is made on a "case-by-case basis." *Ricoh Co. v. Katun Corp.*, No. 03-2612, 2005 WL 6965048, at *1 (D.N.J. Jul. 14, 2005) (granting motion to bifurcate); *see also Barr Lab., Inc. v. Abbott Lab.*, 978 F.2d 98, 115 (3d Cir. 1992) (affirming bifurcation). Due to their complexity, patent cases are routinely bifurcated to promote efficiency and simplify issues. 8 MOORE'S FEDERAL PRACTICE 3D § 42.24[3], at n.5; *Ricoh*, 2005 WL 6965048, at *1 ("In the context of patent cases, experienced judges use bifurcation and trifurcation both to simplify the issues [] and to maintain manageability ....") (quotation omitted); *see also Wyeth v. Abbott Labs.*, No. 08-230 2010 WL 4553545, at *2 (D.N.J. Nov. 3, 2010) (granting motion to bifurcate in case involving multiple patents and multiple accused products).

B. Bifurcation Will Promote Judicial Economy and Reduce the Risk of Prejudice

Jazz requests bifurcation of trial on all claims related to the '730 patent family, as well as a stay of expert discovery on those claims [redacted] Under the current circumstances, Rule 42 strongly favors bifurcation.[5]

[5] [redacted]

First, bifurcation will promote judicial economy. [redacted]

[redacted] *See Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997) ("What is

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6 [redacted]

likely to be sold, or preferably, what will be sold, will ultimately determine whether infringement exists."). [redacted] *See Hines on behalf of Sevier v. Secretary of HHS*, 940 F.2d 1518, 1522 (Fed. Cir. 1991) (Article III of the U.S. Constitution "has been interpreted as barring federal courts from rendering advisory opinions") (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)).

[redacted]

7 [redacted]

[redacted]

Third, bifurcation will minimize prejudice to the parties. [redacted] Roxane itself, moreover, has made the case that it is being required to litigate more claims than are reasonable for trial—bifurcation will more than halve the overall claims-in-suit (41 of 78 asserted claims are in the '730 patent family.)

By contrast, in the absence of bifurcation, Jazz will be severely prejudiced. Expert discovery on the '730 patent family will involve several experts who would not be involved in any of the other pending issues in this case and would involve 41 claims [redacted]

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8 [redacted]

9 [redacted]

[redacted]

Finally, the same reasons that support bifurcation also support staying expert discovery on the '730 patent family claims. *See Akzona Inc. v. E.I. Du Pont de Nemours & Co.*, 607 F. Supp. 227, 232 (D. Del. 1984) ("It is implicit in [Federal Rule] 42(b) that a trial judge who grants bifurcation has the power to limit discovery to issues relevant to the first trial.").[10] [redacted]

IV. CONCLUSION

For the reasons stated above, Jazz respectfully requests that the Court grant its motion to bifurcate claims relating to the REMS patents.

Respectfully submitted,

Dated: December 3, 2013

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[10] The factual issues underlying the claims pertaining to the '730 patent family are also separate and distinct from those underlying the remaining patents-in-suit, which are directed to formulations and methods of treating narcolepsy patients, not REMS.

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